[redacted]

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

Cesare Gianturco

Patent No. 5,041,126 07/244,669

Issued August 20, 1991

ENDOVASCULAR STENT
AND DELIVERY SYSTEM

October 22, 1997

RESPONSE TO REQUIREMENT FOR INFORMATION

Hon. Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231
Sir:

This paper is submitted in support of the Application For Extension Of Patent Term Under 35 U.S.C. § 156, filed July 7, 1997, concerning the above-identified patent. In response to the requirement for information dated September 8, 1997, Cook Incorporated, owner of record of United States Patent No. 5,041,126, by its undersigned agent, encloses herewith the requested documentation regarding the description of the Cook GRII® coronary stent. Specifically, enclosed is an excerpt of PMA Supplement Number 910030, giving a description of the GRII® coronary stent, and a product circular for the GRII® coronary stent.

Notwithstanding the "Company Confidential" markings found in the PMA excerpt, the undersigned hereby states that the excerpt is no longer confidential to Cook Incorporated, and it is intended to become a part of the public file associated with the present application for patent term extension.

device yet maintain or improve its radial strength. A thin spine has also been added to the back of the GR II™ to facilitate proper positioning of the device during deployment of the stent. The catheter shaft material for both the Gianturco-Roubin Flex-Stent™ Coronary Stent and GR II™ Coronary Stent is double-lumen polyethylene. However, unlike the Flex-Stent™ balloon, the GR II™ balloon provides non-compliant, higher pressure material characteristics due to a high density polyethylene material formulation.

To help facilitate stent visualization and precise positioning of the GR II™ stent, a radiopaque marker is affixed to each end of the stent. Previously approved stent/balloon assemblies have relied only on marking systems which were incorporated on the delivery balloon upon which the stent was mounted.

The flat wire design of the GR II™ stent permits a much lower outside diameter profile than the previous Gianturco-Roubin Flex-Stent™ Coronary Stent. Dimensionally, this design feature permits vascular access via smaller guiding catheters (e.g., 6 Fr to 7 Fr) as compared to the large lumen 8 Fr and 9 Fr guiding catheters required for the Gianturco-Roubin Flex-Stent™ Coronary Stent. To assure maximum trackability and performance, a microthin layer (0.0009-inch) of a proprietary polymer is applied to the surface of the stent.

Table 3.2 identifies specific sizes, catalog numbers, and component descriptions of the various sizes of the GR II™ Coronary Stent that are the subject of this premarket approval application.

Table 3.2 Catalog Description of Device System

Catalogue No.	Catheter	Stent
GRO-2.5-20	GRO-2.5-20-NBS	Flat-Preform-#20049-A/1
GRO-3.0-20	GRO-3.0-20-NBS	Flat-Preform-#20049-A/2
GRO-3.5-20	GRO-3.5-20-NBS	Flat-Preform-#20049-A/3
GRO-4.0-20	GRO-4.0-20-NBS	Flat-Preform-#20049-A/4
GRO-3.0-40	GRO-3.0-40-NBS	Flat-Preform-#20049-A/7
GRO-3.5-40	GRO-3.5-40-NBS	Flat-Preform-#20049-A/8
GRO-4.0-40	GRO-4.0-40-NBS	Flat-Preform-#20049-A/9

The principles of operating the GR II™ Coronary Stent are identical to that of the Flex-Stent™ and similar to other metallic stents. The stent is premounted on a balloon catheter, which serves as the delivery catheter. The stent is positioned between two radiopaque marker bands which are located inside the balloon at the proximal and distal tapers of the balloon. The balloon catheter design is consistent with other commercially available PTCA balloon catheters.

Following percutaneous insertion of the catheter through an appropriately sized guiding catheter, the stent/balloon catheter is advanced into position across a coronary lesion. The balloon of the catheter is inflated with contrast medium. As the balloon is inflated, the stent expands. Evacuation of contrast medium from the balloon lumen results in balloon deflation, at which time the balloon catheter is withdrawn, leaving the stent in its expanded form in the vessel.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

C. David Emhardt
Woodward, Emhardt, Naughton, Moriarty & McNett
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis IN 46204-5137

REQUIREMENT FOR INFORMATION

This is in response to the application for patent term extension under 35 U.S.C. § 156, filed July 7, 1997.

The requested information must be submitted within TWO (2) MONTHS from the mail date of this letter. Failure to respond may result in a delay in the processing of the application. Extensions of time under 37 CFR 1.136(a) are NOT permitted.

In order to determine whether a patent is eligible for patent term extension, it is necessary to determine whether the patent to be extended claims the approved product or a method of use of the approved product. In order to assist the Office in this determination, documentation of the description of the product Cook GRII™ Coronary Stent is requested. For example, if a part of the PMA supplement, or an amendment thereto, describes the Cook GRII™ Coronary Stent, then a copy of that description would be of assistance. Furthermore, any available product circulars describing the Cook GRII™ Coronary Stent would also be of assistance.

Correspondence with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: Cook GRII™ Coronary Stent

SEP - 8 1997

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,041,126 was filed on July 7, 1997, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Cook GRII™ Coronary Stent, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: C. David Emhardt
Woodward, Emhardt, Naughton, Moriarty & McNett
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